

STERIS®



May 18, 1999

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Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville, MD 20852

RE: Advanced Notice of Proposed Rulemaking: Irradiation in the Production, Processing, and Handling of Food, 64 Fed. Reg. 7834 (February 17, 1999)
Docket No. 98N-1038

Dear Sir or Madam:

In the above-referenced notice, FDA requested comments on two issues: (1) whether the wording of the current radiation disclosure statement should be revised, and (2) whether such labeling requirements should expire at a specified date in the future. It is our view at STERIS Corporation that the wording of the current disclosure statement should be revised to replace the phrases "treated with radiation" or "treated by irradiation" with "pasteurized" or "cold pasteurized." Further, we believe consumers should know that their food has been treated in a manner that helps ensure its safety, and any expiration of disclosure requirements should be consistent with the public's general understanding of the benefits of the process.

BACKGROUND

STERIS Corporation is a leading provider of contamination prevention, microbial reduction, and infection prevention products, services, and technologies to health care, pharmaceutical, research, and food customers throughout the world. STERIS designs, develops, manufactures, and markets high and low temperature sterilization, washing/disinfection, hand and surface decontamination, and aseptic processing systems. Our wide breadth of products, services, and educational programs offers customers a fully integrated systems approach in addressing their anti-microbial and decontamination requirements.

STERIS Isomedix Services became part of the STERIS family of companies in 1997. STERIS Isomedix Services is one of the leading contract sterilization companies in the industry with over 25 years of experience in irradiation processing of pharmaceuticals, medical devices, foods, and other consumer products. Our irradiation modalities include Gamma and E-beam. STERIS Isomedix Services operates 14 facilities in North America.

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At STERIS, we believe that irradiation has an important and potentially larger role to play in ensuring safe food.

SPECIFIC COMMENTS

FDA had asked whether the current radiation disclosure required, i.e., the radura logo and statement "treated with radiation" or "treated by irradiation", conveys "meaningful information to consumers in a truthful and nonmisleading manner." 64 Fed. Reg. 7834, 7836. While the disclosure may be truthful, it is perceived by consumers as a warning and does not accurately convey the benefits of irradiation. People believe that their exposure to radiation can have adverse health consequences and they may not necessarily understand that irradiated food is not radioactive. The current required labeling and the consumers perception of it may discourage food producers from using irradiation in processing food.

We believe that the current disclosure statements should be changed from, "treated with radiation" or "treated by irradiation" to "pasteurized" or "cold pasteurized." The term pasteurization is familiar to consumers from their exposure to the process as it is used with other food products and is generally viewed as positive. The food safety benefits of irradiation would best be conveyed to consumers by using these statements accompanied by the radura logo. These statements, along with the radura logo would indicate that the food had been processed with irradiation and would not be interpreted as a warning or erroneously associated with the idea that radioactivity is in the food.

With respect to foods containing irradiated ingredients, we believe that consumers will not be misled by the absence of a disclosure unless the irradiated ingredients constitute more than half of the product's ingredients by weight. Therefore, we recommend against the indication of food ingredients as irradiated unless they constitute a major portion (over 50%) of the composite product.

With respect to the radura logo, it is STERIS' view that consumers understand it to be a warning, and that accompanying explanatory text, such as the word "pasteurized" or the phrase "cold pasteurized", is necessary to avoid consumer anxiety and confusion. The disclosure statement requirements should remain in effect until consumers recognize that the radura logo means that foods have been treated with radiation, that irradiation improves the food's safety by killing microbial pathogens and that the food is neither radioactive nor does it present the dangers of harmful radiation if consumed. To be truthful, meaningful and understandable, labeling must convey these facts.

Because of the value of irradiating foods, STERIS believes it is important that the consuming public understand the legitimate role of irradiation in ensuring food safety.

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Accordingly, we call upon the federal government to take a more active role in educating consumers about the food safety benefits of irradiation. Studies have shown that consumers look to public health agencies for sound scientific interpretation of issues relating to health and safety. Every credible government and private health organization, including FDA, USDA, the American Medical Association, the American Dietetic Association and the World Health Organization, has recognized the value of food irradiation as a means of preventing foodborne disease. A consumer education initiative sponsored by reputable government public health agencies in conjunction with industry would greatly impact consumer understanding and acceptance.

STERIS appreciates the opportunity to provide comments on this advance notice of proposed rulemaking and is available to answer questions or provide additional information as required.

Sincerely,

STERIS Corporation

A handwritten signature in black ink, reading "Raymond E. Ursick" with a stylized flourish at the end.

Raymond E. Ursick
Vice President of Regulatory Affairs & Quality Systems